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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,182	05/09/2001	John P. Hamman	Nut-0003	4884

7590 06/18/2003

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EXAMINER
DELACROIX MUIRHEI, CYBILLE

ART UNIT	PAPER NUMBER
1614	7

DATE MAILED: 06/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/852,182	HAMMAN ET AL.	
	Examiner	Art Unit	
	Cybille Delacroix-Muirheid	1614	

-- The MAILING DATE of this communication appears n the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-36 are presented for prosecution on the merits.

Election/Restriction

1. Applicant's election with traverse of Group I, claims 1-18 in Paper No. 6 is acknowledged. The traversal is on the ground(s) that the Examiner has provided no support for the conclusion that the process can be practiced with different compositions such as cyclodextrins or liposomes. Additionally, Applicant contends that the Examiner's statement regarding separate status in the art lacks any factual support. Applicant's arguments have been found to be persuasive. Accordingly, the restriction requirement **is withdrawn**.

Claim Objections

2. Claims 5, 6, 9 and 23 are objected to because of the following informalities: in claim 6, line 2, after "component", the term "comprising" should be cancelled and replaced with --comprises--. In claim 9, line 2, the phrase "selected from the group comprising" should read --selected from the group consisting of--. Claims 5 and 23 are objected to because they recite that "creatine" and "carnitine" are amino acids. However, page 7, first full paragraph describe these compounds as being analogs of certain amino acids. Therefore, Applicant should consider adding such language to claims 1, 5, 19 and 23. For example the phrase --or analogs thereof-- could be added after "amino acid." Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kodera et al., 6,455,273 B1 (102(e)=03/14/01) and Kurtz et al., 5,639,788 and Daravingas et al., 6,235,320 B1 (102(e)=06/06/94) in view of Schwarz et al., 6,149,941 and Mezaache et al., 6,165,512.

Kodera et al. disclose that protein hydrosylates are known compositions, which have excellent functions and properties but have a strong bitterness. Please see col. 1, lines 43-45.

Kurtz et al. disclose specific eatable (materials ingested by humans and other animals, etc.) modified by the addition of taste modifiers comprising a "tastand", wherein Kurtz et al. disclose that the eatable to be modified has a bitter or metallic taste and is selected from the group consisting of amino acids, peptides, polypeptides and proteins. Please see claim 8, col. 3, lines 44-48.

Finally, Daravingas et al. also disclose that protein hydrosylates impart undesirable flavors to food, i.e. yogurt. Please see col. 8, lines 31-33.

Kodera and Kurtz and Daravingas et al. do not specifically disclose masking the bitter and undesirable taste of compositions containing amino acids, peptides, protein and protein hydrosylates with sucralose; however, the Examiner refers to (1) Schwarz et al., which disclose solid pharmaceutical compositions containing an active agent, wherein the compositions may have an improved flavor profile as well as organoleptic sensation in the mouth. This is accomplished by adding flavor improvers such as sucralose to the composition before spray-

drying or fluidized bed granulation. Please see col. 2, lines 46-51; col. 4, lines 5-10, claims 9, 10; and (2) Mezaache et al., which disclose dosage forms containing taste masked ingredients, wherein the dosage forms contain taste masking coatings that contain sweeteners such as sucralose. Please see col. 1, lines 14-17; col. 8, lines 1-4; col. 11, lines 33-51; col. 12, lines 16-23.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the bitter tasting amino acids, peptides, proteins and protein hydrosylate containing compositions of Kodera, Kurtz and Daravingas et al. by "masking" them with the addition of sucralose because Schwarz and Mezaache et al. suggest that sucralose is an effective sweetener useful for masking the unpleasant taste of active ingredients, resulting in a composition with improved flavor and organoleptic properties. Such a modification would have been motivated by the reasonable expectation of producing an amino acid, peptide, protein or protein hydrosylate containing composition, the bitter, unpleasant taste of which is effectively masked by sucralose.

Concerning the claims drawn to specific concentrations of sucralose, since it is well established that the sweetening or masking effect of the sucralose will depend on its concentration in the composition, it would have been obvious to one of ordinary skill in the art to further modify the compositions of the prior art such that the sucralose is present in an amount which is effective to optimize its sweetening or masking effect on the compositions.

Finally, concerning the claims drawn to the specific amino acids (claims 5 and 9), the amino acids, proteins, peptides and polypeptides disclosed in Kurtz et al. would obviously, if not inherently, contain the specific amino acids as claimed by Applicant.

6. Claims 19-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kodera et al., 6,455,273 B1 (102(e)=03/14/01) and Kurtz et al., 5,639,788 and Daravingas et al., 6,235,320 B1 (102(e)=06/06/94) in view of Schwarz et al., 6,149,941 and Mezaache et al., 6,165,512.

Kodera et al. disclose that protein hydrosylates are known compositions, which have excellent functions and properties but have a strong bitterness. Further Kodera et al. disclose a method for producing a protein hydrosylate with low bitterness, by contacting the protein with certain protease enzymes. Please see col. 1, lines 43-45; col. 2, lines 21-31

Kurtz et al. disclose a method of modifying the taste of specific eatables (materials ingested by humans and other animals, etc.) by adding a "tastand", which serves to reduce the bitter or metallic taste of the eatables. Furthermore, Kurtz et al. disclose that the eatables to be modified have a bitter or metallic taste and are selected from the group consisting of amino acids, peptides, polypeptides and proteins. Please see claims 1, 4 and 8, col. 3, lines 44-48.

Finally, Daravingas et al. also disclose that protein hydrosylates impart undesirable flavors to food, i.e. yogurt. Please see col. 8, lines 31-33.

Kodera and Kurtz and Daravingas et al. do not specifically disclose a method for masking the bitter and undesirable taste of amino acids, peptides, protein and protein hydrosylates containing compositions by adding sucralose; however, the Examiner refers to (1) Schwarz et al., which

disclose a method of improving the taste of solid compositions containing one or more active agents, wherein said method involves adding flavor improvers such as sucralose to the composition before spray-drying or fluidized bed granulation. The resulting compositions have an improved flavor profile as well as organoleptic sensation in the mouth. (please see col. 2, lines 46-51; col. 4, lines 5-10, claims 9, 10); and (2) Mezaache et al., which disclose dosage forms containing taste masked ingredients made by a method which, among other steps, involves the use of taste masking coatings that contain sweeteners such as sucralose. Please see col. 1, lines 14-17; col. 8, lines 1-4; col. 11, lines 33-51; col. 12, lines 16-23.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods of the prior art, especially Kodera and Kurtz et al., to include the use of sucralose as a "masking" agent because Schwarz and Mezaache et al. suggest that sucralose is an effective sweetener useful for masking the unpleasant taste of active ingredients, resulting in a composition with improved flavor and organoleptic properties. Such a modification would have been motivated by the reasonable expectation of producing an amino acid, peptide, protein or protein hydrosylate containing composition the bitter, unpleasant taste of which is effectively masked by sucralose.

Concerning the claims drawn to specific concentrations of sucralose, since it is well established that the sweetening or masking effect of the sucralose will depend on its concentration in the composition, it would have been obvious to one of ordinary skill in the art to

further modify the methods of the prior art such that the sucralose is present in an amount which is effective to optimize its sweetening or masking effect on the compositions.

Finally, concerning the claims drawn to the specific amino acids (claims 23 and 27), the amino acids, proteins, peptides and polypeptides disclosed in Kurtz et al. would obviously, if not inherently, contain the specific amino acids as claimed by Applicant.

Conclusion

Claims 1-36 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

CDM

June 12, 2003

Cybille Delacroix-Muirheid
Patent Examiner Group 1600